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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/545,334	04/07/2000	Jeffrey E. Habben	0803	9587
27310	7590	12/17/2003	EXAMINER	
PIONEER HI-BRED INTERNATIONAL INC. 7100 N.W. 62ND AVENUE P.O. BOX 1000 JOHNSTON, IA 50131			BAUM, STUART F	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/545,334	HABBen ET AL.	
	Examiner	Art Unit	
	Stuart F. Baum	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7-11, 13, 14, 17, 20-24, 26, 27, 30, 32, 33, 35, 38, 39, 42-56 and 58-63 is/are pending in the application.
- 4a) Of the above claim(s) 9, 11, 22, 24, 34, 36, 48, 50-52, 54-56, 58 and 59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7, 8, 10, 13, 14, 17, 20, 21, 23, 26, 27, 30, 32, 33, 35, 38, 39, 42-47, 49, 53 and 60-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/17/2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed 9/15/2003 has been entered.

Claims 1-4, 7-11, 13-14, 17, 20-24, 26-27, 30, 32-33, 35, 38-39, 42-56, and 58-63 are pending.

Claims 5-6, 12, 15-16, 18-19, 25, 28-29, 31, 37, 40-41, and 57 have been canceled.

Claims 60-63 have been added.

Claims 9, 11, 22, 24, 34, 36, 48, 50-52, 54-56, and 58-59 have been withdrawn from consideration because the claims are drawn to non-elected inventions.

2. Claims 1-4, 7-8, 10, 13-14, 17, 20-21, 23, 26-27, 30, 32-33, 35, 38-39, 42-47, 49, 53, and 60-63 are examined in the present office action.

3. Rejections and objections not set forth below are withdrawn.

4. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

5. This application contains claims 9, 11, 22, 24, 34, 36, 48, 50-52, 54-56, and 58-59 drawn to a nonelected invention. A complete reply to the final rejection must include cancelation of nonelected claims (37 CFR 1.144) See MPEP § 821.01.

New Matter

6. Claims 1-4, 7-8, 10, 17, 20-21, 23, 30, 32-33, 35, 42-47, and 60-63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

Art Unit: 1638

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are all drawn to a cytokinin catabolic enzyme. Claims drawn to a cytokinin catabolic enzyme or a method for producing fertile, transgenic plants in which the expression of a catabolic enzyme is modified, do not have support in the presently filed application and are considered new matter.

Claims drawn to "isogenic" and "maternal tissue" do not have support in the presently filed application and are considered new matter.

Indefiniteness

7. Claims 1-4, 7-8, 10, 13-14, 17, 20-21, 23, 26-27, 30, 32-33, 35, 38-39, 42-47, 49, 53, and 60-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection includes dependent claims.

In claim 1, the metes and bounds of "related maternal tissue" have not been defined. It is unclear what tissues are considered "maternal". Would all the tissues of the flower, including the flower anlagen, be considered "maternal"?

In claim 1, the metes and bounds of "cytokinin biosynthetic enzyme" and cytokinin catabolic enzyme" have not been defined. How does one measure or asses if an enzyme is considered to be a "cytokinin biosynthetic enzyme" or a "cytokinin catabolic enzyme"? What enzymes in which specific pathways are encompassed by the claimed recitations?

Art Unit: 1638

Applicants assert that the term “cytokinin biosynthetic enzyme” is unambiguous to one of skill in the art. Applicants contend that it could be conceivable that every physiological process in an organism is in some way related to biosynthesis of a single, specific product, but that such an extrapolation would render meaningless much of the vocabulary of physiology and would be unreasonable to one of skill in the art. Applicants contend that the enzymes listed on pages 874-877 of Biochemistry & Molecular Biology of Plants (Buchanan, Gruissem & Jones, eds., American Society of Plant Physiologists, Rockville, MD, 2000) represent the state of knowledge of cytokinin biosynthesis at the time the application was filed. Applicants submit that the enzymes therein identified as involved in cytokinin biosynthesis comprise “cytokinin biosynthetic enzymes” of the invention.

The Office notes that a copy of the recited text has not been received, and as such, is unable to evaluate Applicants’ referenced pages. The rejection is maintained.

Written Description

8. Claims 1-4, 7-8, 10, 13, 17, 20-21, 23, 26, 30, 32-33, 35, 38, 42-47, 49, and 60-63 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 3/27/2003. Applicant’s arguments filed 9/15/2003 have been fully considered but they are not persuasive.

Art Unit: 1638

Applicants contend that an adequate number of cytokinin modulating genes are described. The sequence listing provides both ipt and cytokinin oxidase sequences and other cytokinin modulating genes are referred to generally in the specification on page 3, lines 8-17. Applicants contend that the description would reasonably convey to the skilled artisan what is encompassed by the invention. Applicants contend that the Guidelines state that a single species may, in some instances, provide an adequate written description of a generic claim.

The Office contends that Applicants claims are broadly drawn to cytokinin biosynthetic or cytokinin catabolic enzymes. Applicants are required to disclose a representative number of cytokinin biosynthetic or cytokinin catabolic enzyme DNA and amino acid sequences or Applicants are to disclose the structural features common to cytokinin biosynthetic or cytokinin catabolic enzymes. Applicants fail on both counts. Moreover, Applicants fail to draw the nexus between structure and function that defines their claimed genus of cytokinin biosynthetic or cytokinin catabolic enzymes. To have an adequate written description for cytokinin biosynthetic and cytokinin catabolic enzymes, Applicant needs to disclose a representative number of species, allelic variants, mutants of each enzyme to allow one skilled in the art to reliably predict the structure of other species, allelic variants, and mutants not disclosed of each of the enzymes. Disclosing one enzyme or multiple structures of one enzyme is not an adequate written description for all “cytokinin biosynthetic” and “cytokinin catabolic” enzymes.

Art Unit: 1638

Written Description #2

9. Claims 1-4, 7-8, 10, 13-14, 17, 20-21, 23, 26-27, 30, 32-33, 35, 38-39, 42-47, 49, 53, and 60-63 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method for producing fertile, transgenic plants, a fertile transgenic plant, an isolated recombinant DNA molecule and a method for improving stress tolerance and yield stability in plants, all of which comprising a cytokinin biosynthetic enzyme wherein the cytokinin biosynthetic enzyme is isopentenyl transferase.

Applicants have only taught bacterial isopentenyl transferases (ipts) but Applicants' claims encompass all ipts including plant ipts. Applicants have fulfilled the written description requirement for bacterial ipts but not for all ipts, including plant ipts. The Applicants do not identify essential regions of ipts. The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a

Art Unit: 1638

recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus.” *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Applicants fail to describe a representative number of ipt encoding nucleic acid molecules from plants which fall within the scope of the claimed ipt genus. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of ipt. Furthermore, given the lack of description of the necessary elements essential for ipt, it remains unclear what features identify an ipt. Since the genus of ipt has not been described by specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims.

Enablement

10. Claims 1-4, 7-8, 10, 13, 17, 20-21, 23, 26, 30, 32-33, 35, 38, 42-47, 49, and 60-63 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a maize plant transformed with a bacterial isopentenyl transferase encoding polynucleotide (ipt) to produce seeds with increased zeatin levels or expression, increased seed set compared to plants transformed with other genes (page 56, Table 2) and seeds that exhibit vivipary, does not reasonably provide enablement for claims drawn to a method of producing a transgenic plant wherein expression of a polynucleotide encoding a cytokinin biosynthetic or cytokinin catabolic enzyme or a plant ipt, is modified; or a transgenic plant, an isolated recombinant DNA molecule, or method for improving stress tolerance and yield stability all of which comprising a cytokinin biosynthetic enzyme, cytokinin catabolic enzyme or a plant ipt encoding nucleic acid. This

Art Unit: 1638

rejection is maintained for the reasons of record set forth in the Official action mailed 3/27/2003.

Applicant's arguments filed 9/15/2003 have been fully considered but they are not persuasive.

Applicants contend that they have narrowed the claims by replacing "modulating" with cytokinin biosynthetic and cytokinin catabolic enzymes. Applicants contend that the specification provides support for cytokinin biosynthetic enzymes. Applicants contend that the Kusaba et al reference cited by the Examiner as teaching unpredictable results, used a constitutive promoter which is different than the instant claims, which are drawn to a tissue-preferred, tissue-specific, or temporally-regulated promoter. Applicants contend that the end2 promoter is disclosed in applications to which the present application claims benefit.

The Office acknowledges Applicants narrowing of the claims by replacing "modulating" with cytokinin biosynthetic and cytokinin catabolic enzymes. Based on Applicants disclosure and the state of the art as discussed previously, undue trial and error experimentation would be required by one skilled in the art to isolate and screen through the myriad of sequences that are encompassed by Applicants' broad claim language. The Office contends that Kasaba et al and Binns (as cited in the previous office action) both teach unpredictability and is applicable to the present application, even though they use the 35S constitutive promoter. The Office contends that Applicants have only exemplified one sequence and yet, Applicant is claiming all cytokinin biosynthetic and cytokinin catabolic enzymes. Applicants have not exemplified a representative number of cytokinin biosynthetic and cytokinin catabolic enzymes to support the generic claims.

Applicants claims are drawn to modifying the expression of a nucleic acid encoding a cytokinin biosynthetic, cytokinin catabolic or ipt polypeptide. Modifying encompasses both increases and decreases, but Applicant has only exemplified increasing expression. Decreasing

Art Unit: 1638

expression utilizes different method steps and molecular mechanisms of which Applicant is not enabled.

Applicants claim a method for improving stress tolerance and yield stability in plants comprising transforming a plant with a nucleic acid encoding any cytokinin biosynthetic or cytokinin catabolic enzyme. Applicants have not reduced to practice their invention. Stress tolerance and yield stability are complex, highly regulated processes involving multiple proteins in multiple pathways. How stress tolerance and yield stability occurs is not fully understood to date. It is highly unlikely that one protein controls the stress tolerance and yield stability process. More likely, there are multiple proteins with redundant functions that are involved in the process to ensure stress tolerance and yield stability occurs at the appropriate time and place. In addition, if stress tolerance and yield stability were controlled by a single protein, then mutagenesis experiments should have already uncovered the gene responsible for encoding this protein. But to date, no such gene has been uncovered by chemical or insertional mutageneses. Applicants have not shown that any cytokinin biosynthetic or cytokinin catabolic enzyme alone can regulate or control stress tolerance and yield stability by itself. It is unpredictable what other proteins are required. Given the lack of guidance and the unpredictability of what other proteins are required, excessive experimentation would be required to make and use the claimed invention.

35 USC § 102

11. Claims 1-2, 4, 13-14, 17, 26-27, 30, 38-39, 42-43, 49, and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Houck et al (January, 1993, U.S. Patent Number

Art Unit: 1638

5,177,307). This rejection is maintained for the reasons of record set forth in the Official action mailed 3/27/2003. Applicant's arguments filed 9/15/2003 have been fully considered but they are not persuasive.

Applicants contend that the present application is distinct from the Houck et al patent as to several elements and thus is not anticipated. Applicants contend that Houck et al is directed to cytokinin modification so as to increase fruit weight and/or alter the rate of fruit ripening, whereas the present application provides utilities of improved seed size, decreased tip kernel abortion and increased seed set during unfavorable environmental conditions. Applicants contend that Houck et al used tomato which is a "fruit-bearing plant" and that the present application is drawn to Zea Mays which is not considered to be a "fruit-bearing plant". Applicants contend that the Examiner's rejection of claims drawn to a method that results in improved stress tolerance and yield stability as being an inherent feature of Houck et al is not proper (page 14-15, §102).

The Office contends that the method as recited in the present claims is of the same scope as that of Houck et al. The stated outcome may be different but the claimed method steps are the same. In response to applicant's argument that the reference fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., utilities of improved seed size, decreased tip kernel abortion and increased seed set during unfavorable environmental conditions) are not recited in the rejected claim(s). Applicants' claims are drawn to a plant but Applicants' arguments are drawn to corn or fruit bearing plants. Applicants' arguments are not commensurate in scope with the claimed invention and although the claims are interpreted in light of the specification, limitations from the specification are not read into the

Art Unit: 1638

claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Lastly, the Office contends that the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. MPEP 2112.

Claim Rejections - 35 USC § 103

12. Claims 1-4, 8, 10, 13-14, 17, 21, 23, 26-27, 30, 33, 35, 38-39, 42-47, 49, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houck et al (January, 1993, U.S. Patent Number 5,177,307) as applied to claims 1-2, 4, 13-14, 17, 26-27, 30, 38-39, 42-43, 49, and 53 above, and further in view of Tomes et al (March, 1999, U.S. Patent Number 5,877,400).

Applicants contend that a finding of obviousness must be supported by some suggestion, motivation, or teaching in the prior art that would have led a person of ordinary skill in the art to select the references and combine them in the way that would produce the claimed invention. Applicants contend that U.S. Patent 5,177,307 is directed to cytokinin modification so as to increase fruit weight and/or alter the rate of fruit ripening. The tomato is the species of choice in the application and the application teaches other "fruit-bearing plants" in which the plant parts of interest are derived from the ovary wall. Applicants contend that no monocot species are included in the patent's list of species. Applicants contend that the combination of patents 5,177,307 and 5,877,400 actually teach away from the current invention because the 5,877,400 patent is directed to modification of fruit development, in particular, altering the timing of development so as to minimize seed production. Applicants contend that "one skilled in the art of the present invention would not likely be motivated to combine the disclosures of 5,877,400 (providing promoters to be used in minimizing seed production) and 5,177,307 (providing a

Art Unit: 1638

means to modify fruit ripening) to create constructs, methods, and plants directed toward increased grain (i.e. seed, not fruit) yield. Further, the present application is directed toward plant performance in an unfavorable environment, a factor which is not suggested in either patent” (pages 15-16, §103).

The Office contends that the motivation to combine the two patents is presented in both patents. The 5,177,307 patent teaches increased cytokinins increase the mass of seeds which improves seed set and increases yield and increased cytokinin levels ameliorate the effects of senescence which can be brought on by stress (column 4, lines 24-27; column 3, lines 1-5). And the 5,177,307 patent teaches using tissue specific promoters so as to modulate cytokinin levels in specific tissues at a particular time of development (column 3, lines 1-5). The 5,877,400 patent teaches promoters that can be used to express proteins in the embryo and endosperm. The Office contends that the response to “fruit-bearing plants” is discussed in the “102” section above. The Office contends that the two patents do not teach away from Applicants’ invention. Applicants’ arguments are based on the disclosure of the abstract. The Office contends that reading the body of the patents teaches the necessary information as discussed above. The Office contends that the 5,177,307 patent teaches ameliorating the effects of “stress” (as discussed previously) which is to say an “unfavorable environment”.

13. No claims are allowed.

Art Unit: 1638

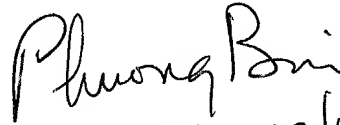
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 703-305-6997. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Stuart F. Baum Ph.D.

December 12, 2003


PHUONG T. BUI
PRIMARY EXAMINER 12/12/03